REMARKS

Claim 4 was rejected under 35 U.S.C. 102(b) as being anticipated by White (U.S. Patent #5,237,520). This rejection is respectfully traversed.

In the Office Action, we read: 'Applicant argues that White does not mention corrective" footwear. However, White discloses such; (see "custom footwear products could include items such as custom fit insoles, heel cups, metatarsal support, volume adjustment shims, and the like...custom footwear could include boots, shoes, and other various forms of footwear.'

As shown in the Office Action, it is true that the instant application states, '...custom orthotics, custom shoes and custom sandals, all referred to herein as "corrective orthotics".' However, the Office Action fails to report an important part of the *same sentence*: "...to aid in the correction or prevention of malformations of the feet." In other words, corrective orthotics are not simply custom made footwear, they are custom-made for prevention and/or correction.

According to the MPEP, §608.01(o), "The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import." The meaning of the term "corrective orthotics" was given (see above). This meaning (as will be shown) does not deviate from the ordinary and customary meaning of the term according to medical dictionaries and those of ordinary skill in this art.

The following a segment from LexisNexis as a part of a court ruling is submitted. .

Please note the highlighted portions in the segment, below.

*388 F.3d 858, *; 2004 U.S. App. LEXIS 22738, **;*

73 U.S.P.Q.2D (BNA) 1011

C.R. BARD, INC. and DAVOL INC., Plaintiffs-Appellants, v. UNITED STATES SURGICAL CORP., Defendant-Appellee.

04-1135

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

388 F.3d 858; 2004 U.S. App. LEXIS 22738; 73 U.S.P.Q.2D (BNA) 1011

October 29, 2004, Decided

Language in some of our recent cases, however, suggests that the intrinsic record, except for the claims, should be consulted only after the ordinary and customary meaning of claim terms to persons skilled in the pertinent art is determined. See, e.g., Tex .Digital Sys., Inc. v. Telegenix ,Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002), cert. denied, 538 U.S. 1058, 155 L. Ed. 2d 1108, 123 S. Ct. 2230 (2003). The language in these cases emphasizes technical and general-usage dictionaries in determining the ordinary meaning. Id. Under this approach, where the ordinary meaning of a claim term is thus evident, the inventor's written description of the invention, for example, is relevant and controlling insofar as it provides clear lexicography or disavowal of the ordinary meaning. See id. ("The presumption in favor of a [**10] dictionary definition [of a claim term] will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning. Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.").

The term *orthotic device* is defined in the Medical Dictionary (http://medical-dictionary.com/) as: Apparatus used to support, align, prevent, or correct deformities or to improve the function of movable parts of the body. This is very different than custom footwear, padded insoles or inserts for comfort which does not also provide correction. White discloses "providing custom fit footwear" (Field of the Invention and elsewhere) and does not disclose the use of his invention for corrective orthotics.

A reference showing how those skilled in the pertinent art define the terms "orthotic device" and "orthotics" is included as Exhibit A. In particular, the title of the article is includes "Orthotic Device." On page 466, first column near the top of the page, we read, "The purpose of this study was to evaluate the change in the Q-angle measurement in patients with bilateral hyperpronation of the foot after insertion of the custom-made orthotics." Under METHODS in the same column, toward the middle of the page, we read, "An orthotic cast was made for both feet by using a standard Foot Levelers (Roanoke, Va) casting kit and standard casting protocol. The cast was made for a full-length, custom-made, flexible orthotic." At the bottom of that same column, we read, "Because we were searching for an immediate effect on the Q-angle

subsequent to the insertion of the orthotics…" Results of the corrections after insertion of the custom orthotics are summarized in Tables 1, 2, and 3 (pages 467–469). Under CONCLUSION in the first column of page 469, we read, "Excessive pronation in Q-angle asymmetries can be effectively controlled or corrected by using orthotic devices." All the above quotes point to the correction of abnormalities of the patients' feet. It is clear that these orthotics are:

1. custom made,
2. built for correction or prevention of abnormalities, and
3. not built (solely) for "fit."

White did not disclose an apparatus for obtaining measurements, observations, and color differences from the scan and computer necessary for constructing *corrective* footwear [step (c)].

White mentions arch supports and "fit aids." He also discloses custom footwear for a particular customer. However, *custom* should not be confused for *corrective*. Custom footwear should "fit" a wearer better than off-the-shelf footwear, but custom footwear that is not also *corrective* footwear does nothing to correct for or prevent foot abnormalities and much of the resulting discomfort. White does not disclose the construction of corrective footwear.

In particular, in the *Field of the Invention* section of White, we find: "This system thereby enables more accurate and efficient production of footwear and lasts for the *general public consumption*" (emphasis added). This is counter to the invention disclosed in the present application and claims. It would be absurd to consider providing *corrective* footwear for "general public consumption," as corrective footwear, by definition, must be constructed specifically for a particular client.

Moreover, the measured data extracted from a foot scan (see measurements 1–17 on page 6 of the instant application) to produce corrective orthotics and footwear are necessarily different from those needed for custom footwear, produced only for comfort, not correction.

Claim 4 was previously amended to specify, within the steps of the claim, that measurements are taken for the purpose of constructing corrective orthotics and footwear.

As it is evident that White did not anticipate step (c) of previously amended claim

4, it is believed independent claim 4 is allowable.

Claims 1–3 were rejected under 35 U.S.C. 103(a) as being unpatentable over White in view of Baum (U.S. Patent 6,141,889). This rejection is respectfully traversed.

The Office Action, again, states that "White discloses a method for obtaining measurements for construction corrective orthotics..." As was argued above, White does not disclose using his invention for the construction of corrective footwear, but only custom footwear. The argument above shows that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of White by having the patient stand normally as claimed in claim 1 of the instant invention because White did not disclose the use of his invention for constructing corrective footwear.

Claims 2 and 3, depending on claim 1, are expected also to be allowable as claim 1 is believed to be allowable.

For the above reasons, the Applicant is of the opinion that all claims 1–4 are now allowable, and a notice to that effect is earnestly solicited.

Respectfully submitted,

Kent S. Greenawalt

Feb. 16, 2005
Date

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Exhibit A

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Dedicated to the Advancement of Chiropractic Health Care Principles and Practice

Mosby

Exhibit A

Immediate Changes in the Quadriceps Femoris Angle After Insertion of an Orthotic Device

D. Robert Kuhn, DC,[a] Terry R. Yochum, DC,[b] Anton R. Cherry,[c] and Sean S. Rodgers[c]

ABSTRACT

Objective: To measure changes in the quadriceps femoris angle (Q-angle) after the insertion of full-length flexible orthotics.

Setting: Outpatient health center of Logan College of Chiropractic.

Subjects: A total of 40 male subjects were included in the study population. The selected population all demonstrated bilateral pes planus or hyperpronation syndrome.

Design: Before-after trial.

Method: A cohort demonstrating bilateral hyperpronation was recruited. The subjects were cast according to standard protocols provided by the manufacturer. Subject right and left Q-angles were measured with and without the orthotic in place. The landmarks used were marked with a permanent marker, and great care was taken to accurately assess the angles formed. The evaluator was not told whether the measure was before or after orthotic insertion. A modified quailcraft goniometer was used.

Data Analysis: The data set was collected and assessed by the *t* test.

Results: Thirty-nine of 40 test subjects showed reduced Q-angle, which was in the direction of correction. A 2-tailed matched sample showed statistically significant mean reduction in Q-angle measures. There was a minority of patients who showed asymmetrical Q-angle measures. Within this group there was greater symmetry of Q-angle measures after placement of the orthotic.

Conclusion: Insertion of full-length, flexible orthotic devices significantly improves the Q-angle in hyperpronating male subjects. If the literature accurately links an increase in the Q-angle with a predisposition for knee injury, then the possibility of long-term benefits following the use of flexible orthotics exists. More research is required to determine whether these biomechanical changes are maintained after use of these orthotics. (J Manipulative Physiol Ther 2002;25:465-70)

Key Indexing Terms: *Q-angle; Orthotic Devices; Pes Planus*

Introduction

Hyperpronation of the foot causes many different stresses on the lower extremity joints and soft tissues.[1] This changes the quadriceps femoris angle (Q-angle), which has been associated with chondromalacia patella and lateral displacement of the patella.[1] The Q-angle has been defined as the angle formed by the line connecting the anterior superior iliac spine (ASIS) with the center of the patella and the line connecting the tibial tuberosity to the center of the patella.[1,2]

Normal mean values for the Q-angle are 13.5° ± 4.5° in healthy subjects between 18 and 35 years of age.[1] Comparatively, women have a larger mean Q-angle of 15.8° ± 4.5° than men (11.2° ± 4.5°).[1]

There have been a number of studies regarding the Q-angle and its relationship to anterior knee pain, standing and supine measurements, force on the patella in the frontal plane, shin splints, and others.[2] However, we were unable to

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locate studies that examined the effects of a full-length, custom-made, flexible orthotic on the Q-angle. The purpose of this study was to evaluate the change in the Q-angle measurement in patients with bilateral hyperpronation of the foot after insertion of a custom-made orthotic.

Methods

The study population was derived from a sample of male students enrolled at Logan College of Chiropractic and patients from the Montgomery Health Center. Inclusion criteria consisted of male subjects with bilateral hyperpronation who were asymptomatic and had no history of known ankle surgery. The selection of only male patients helped homogenize our study population and served to eliminate any confounding variables arising from different normal Q-angle values for men and women. A total of 40 men were included in the study population, and each subject read and signed a consent form which had been approved by the Logan College of Chiropractic Research Committee.

To determine whether subjects showed bilateral hyperpronation, the following examination protocol was used. The subjects were observed for any evidence of external rotation or toe-out during the plant phase of gait, their shoes were examined for excessive lateral wear, evaluation for Achilles tendon bowing was made, and observation of the height of the medial arch during non–weight-bearing and weight-bearing conditions was made. The height of the arch was assessed in both weight bearing and non–weight bearing. The results were recorded in millimeters. This constitutes the navicular drop test, as described by Brody.[3]

An orthotic cast was made for both feet by using a standard Foot Levelers (Roanoke, Va) casting kit and standard casting protocol. The cast was made for a full-length, custom-made, flexible orthotic. The Q-angle was measured with a 12-inch goniometer with a 24-inch extension arm. The extension arm was made of clear plastic and was ⅛-inch thick, 2 inches wide, and 24 inches long. The subjects' Q-angles were measured in a standing extended knee position in their daily footwear. One examiner was responsible for the measuring of the Q-angle. When the examiner achieved 2 identical measures, the Q-angle for that limb was recorded. The landmarks used to enhance accuracy of the Q-angle measure were as follows. A single dot was placed on the skin over the center of both patellae with a grease pencil, followed by the marking of this skin over the tibial tuberosity and the anterior superior iliac spine bilaterally. The center axis of the goniometer was placed over the patellar dot, with the short arm of the device directed toward the tibial tuberosity and the extended arm directed at the ASIS. Each subject was measured with and without the orthotics in place in the manner previously described. Because we were searching for an immediate effect on the Q-angle subsequent to the insertion of the orthotics, the order in which these measurements were obtained did not matter. Thus, the evaluator responsible for measuring the Q-angle was not informed about whether the exam was being performed with or without the orthotics in place. A separate investigator was responsible for the flow of subjects and recording the results in the appropriate category. The results were recorded in "before orthotic insertion" and "after orthotic insertion" categories. Each of these was done for the right and left limb. The data set was collected and assessed by using the t test program in Microsoft Excel (Redmond, Wash).

Results

Forty subjects had a mean Q-angle of 12.1° ± 2.6° on the left and 11.8° ± 2.4° on the right, with a range of 8° to 19°. After insertion of the orthotics, subjects had a mean Q-angle of 9.6° ± 2.5° on the left and 9.5° ± 2.2° on the right, with a range of 5° to 18°. This represents a significant mean reduction of the Q-angle by 2.5° [2-tailed, matched sample, $t\ (39) = -7.31, P < .01$] on the left and 2.3° and 2-tailed matched sample, [$t\ (39) = -9.25, P < .01$)] on the right (Tables 1, 2, and 3).

Before orthotic insertion, there was a 2.3° mean asymmetry between the left and right Q-angle within subjects. After orthotic insertion, there was a 1.4° mean asymmetry between Q-angles. This resulted in a significant decrease of .9° [1-tailed, matched sample, $t\ (39) = -3.26, P < .0$] in the left and right asymmetry of the Q-angles within the population. Furthermore, the population with a Q-angle asymmetry greater than 4° (n = 8) realized a larger reduction in Q-angle asymmetry after orthotic insertion (mean before, 4.9°; mean after, 2.1°). A larger sample size is necessary to establish statistical significance. We feel this trend may be important for individuals experiencing altered lower extremity function associated with a large asymmetry in right and left Q-angle measurements.

Discussion

An increase in the Q-angle can occur as a result of internal femoral torsion and excessive foot pronation, which may cause genu valgum or coxa vera. Hyperpronation leads to internal tibial rotation, followed by compensatory internal rotation of the femur, resulting in an increase in the lateral tracking of the patella.[4,5] This excessive tibial rotation transmits abnormal forces upward to the knee, changing the force vectors of the quadriceps muscle, and causes lateral displacement of the patella.[4,5] As the patella displaces laterally, the Q-angle is subsequently increased. As the patella tracks over the femoral condyles, erosion of the patellar and femoral cartilage can occur. In addition, the hyperpronated foot may produce a preloading stress on the anterior cruciate ligament, thus rendering it susceptible to injury.[5] Asymmetrical pronation patterns have been shown to produce faulty pelvic biomechanics.[6]

Table 1. Q-angle study data—Left

Subject	Q-Angle$_1$	(Q-Angle$_1$)^2	Q-Angle$_2$	(Q-Angle$_2$)^2	Q-Angle$_\Delta$	(Q-Angle$_\Delta$)^2	
1	8	64	12	144	4	16	
2	14	196	13	169−	−1	1	0 888
3	18	324	13	169−	−5	25	0 9
4	10	100	11	121	1	1	1 000000
5	16	256	13	169−	−3	9	1 11111
6	11	121	10	100	−1	1	1 2222222222 22
7	10	100	10	100	0	0	1 33
8	8	64	5	25	−3	9	1 444
9	8	64	8	64	0	0	1 55
10	12	144	10	100	−2	4	1 666
11	12	144	7	49	−5	25	1
12	15	225	9	81	−6	36	1 8
13	13	169	9	81	−4	16	1 9
14	13	169	10	100	−3	9	
15	14	196	9	81	−5	25	0 5
16	11	121	8	64	−3	9	0 6
17	12	144	8	64	−4	16	0 7777
18	10	100	8	64−	−2	4	0 8888888888
19	12	144	8	64	−4	16	0 99999
20	11	121	9	81−	−2	4	1 00000000
21	16	256	13	169	−3	9	1 1111
22	12	144	8	64	−4	16	1 2
23	12	144	8	64	−4	16	1 3333
24	12	144	10	100	−2	4	1 4
25	12	144	9	81	−3	9	1
26	10	100	10	100	0	0	1
27	12	144	7	49	−5	25	1
28	12	144	11	121	−1	1	1 8
29	11	121	8	64	−3	9	
30	12	144	7	49	−5	25	
31	10	100	6	36	−4	16	
32	15	225	10	100	−5	25	
33	12	144	11	121	−1	1	
34	10	100	10	100	0	0	
35	10	100	8	64	−2	4	
36	16	256	14	196	−2	4	
37	9	81	8	64	−1	1	
38	14	196	7	49	−7	49	
39	11	121	11	121	0	0	
40	19	361	18	324	−1	1	
41	19	361	18	324	−1	1	
Sum	485	6135	384	3926	−101	441	$t = -7.31$
Mean	12.13		9.60		−2.53		$P < .01$
SD	2.55		2.48		2.18		

Research has suggested overpronation is correlated with impaired proprioceptive feedback. Aberrant lower extremity biomechanics alters postural reflexes, causing the patient to rely on visual input to control postural stability.[7] Furthermore, abnormal mechanoreceptor activity of muscles, tendons, and ligaments has been found to affect dynamic equilibrium as well as visceral function.[8]

Previous and current research suggests that the hyperpronated foot is an etiologic factor in many lower extremity complaints. These include foot pain, knee pain, hip pain, and low back pain.[6] Because of the dynamic nature of bone, abnormal stress results in hypertrophic changes in the osseous structures.[9] It has been shown that abnormal pedal mechanics results in bone marrow edema observed with magnetic resonance imaging in the weight-bearing bones of the lower extremity.[10] This study by Schweitzer and White showed early evidence of physiologic change in the bones when abnormal biomechanics were induced. Furthermore, when a portion of their sample population was scanned after returning to normal lower extremity functional status, there

EXHIBIT A

Table 2. *Q-angle study data—Right*

Subject	$Q\text{-Angle}_1$	$(Q\text{-Angle}_1)^2$	$Q\text{-Angle}_2$	$(Q\text{-Angle}_2)^2$	$Q\text{-Angle}_\Delta$	$(Q\text{-Angle}_\Delta)^2$	
1	15	225	12	144	−3	9	
2	12	144	11	121	−1	1	0 888
3	16	256	15	225	−1	1	0 9999
4	14	196	12	144	−2	4	1 000000
5	16	256	14	196	−2	4	1 1111111
6	16	256	12	144	−4	16	1 222222
7	8	64	10	100	2	4	1 33333
8	12	144	9	81	−3	9	1 444
9	10	100	7	49	−3	9	1 55
10	15	225	14	196	−1	1	1 666
11	10	100	8	64	−2	4	1 7
12	12	144	8	64	−4	16	
13	12	144	10	100	−2	4	
14	11	121	10	100	−1	1	0 6
15	13	169	10	100	−3	9	0 77777
16	11	121	9	81	−2	4	0 88888888 8
17	14	196	8	64	−6	36	0 99999999 9
18	11	121	7	49	−4	16	1 00000000
19	8	64	7	49	−1	1	1 1
20	9	81	6	36	−3	9	1 222
21	12	144	10	100	−2	4	1
22	10	100	9	81	−1	1	1 44
23	13	169	9	81	−4	16	1 55
24	11	121	9	81	−2	4	
25	13	169	8	64	−5	25	
26	9	81	10	100	1	1	
27	9	81	7	49	−2	4	
28	14	196	10	100	−4	16	
29	10	100	8	64	−2	4	
30	11	121	8	64	−3	9	
31	8	64	8	64	0	0	
32	13	169	9	81	−4	16	
33	13	169	9	81	−4	16	
34	11	121	9	81	−2	4	
35	12	144	10	100	−2	4	
36	10	100	9	81	−1	1	
37	11	121	7	49	−4	16	
38	10	100	8	64	−2	4	
39	9	81	8	64	−1	1	
40	17	289	15	225	−2	4	
Sum	471	5767	379	3781	−92	308	$t = -9.25$
Mean	11.78		9.48		−2.30		$P < .01$
SD	2.38		2.21		1.57		

was evidence of normal bone marrow signal, with no evidence of edema. The assessment of lower extremity biomechanical dysfunction therefore requires a complete examination of the entire kinetic chain in both static and motion analysis, with close inspection of the foot-ankle complex. The use of custom-made flexible orthotics can stabilize the pes planus foot and restore the optimal degree of pronation. Reduction of pronation thereby decreases the amount of internal rotation of the tibia and femur, with a subsequent reduction in the Q-angle.

D'Amico and Rubin[11] demonstrated an average reduction of 6° in the quadriceps angle with the use of orthotic devices. Similar findings were obtained in this study. The use of full-length, custom-made, flexible orthotics showed a 2.4° average reduction in Q-angle bilaterally and a .9° average reduction in Q-angle asymmetry in the examined

Exhibit A

Table 3. *Q-angle study data—ΔR&L*

Subject	$\Delta R\&L_1$	$(\Delta R\&L_1)^2$	$\Delta R\&L_2$	$(\Delta R\&L_2)^2$	$\Delta R\&L_\Delta$	$(\Delta R\&L_\Delta)^2$	
1	7	49	0	0	−7	49	
2	2	4	2	4	0	0	
3	2	4	2	4	0	0	
4	4	16	1	1	−3	9	
5	0	0	1	1	1	1	
6	5	25	2	4	−3	9	
7	2	4	0	0	−2	4	
8	4	16	4	16	0	0	
9	2	4	1	1	−1	1	
10	3	9	4	16	1	1	
11	2	4	1	1	−1	1	
12	3	9	1	1	−2	4	
13	1	1	1	1	0	0	
14	2	4	0	0	−2	4	
15	1	1	1	1	0	0	
16	0	0	1	1	1	1	
17	2	4	0	0	−2	4	
18	1	1	1	11	0	0	
19	4	16	1	9	−3	9	
20	2	4	3	9	1	1	
21	4	16	3	1	−1	1	
22	2	4	1	1	−1	1	
23	1	1	1	1	0	0	
24	1	1	1	1	0	0	
25	1	1	1	1	0	0	
26	1	1	0	0	−1	1	
27	3	9	0	0	−3	9	
28	2	4	1	1	−1	1	
29	1	1	0	0	−1	1	
30	1	1	1	1	0	0	
31	2	4	2	4	0	0	
32	2	4	1	1	−1	1	
33	1	1	2	4	1	1	
34	1	1	1	1	0	0	
35	2	4	2	4	0	0	
36	6	36	5	25	−1	1	
37	2	4	1	1	−1	1	
38	4	16	1	1	−3	9	
39	2	4	3	9	1	1	
40	2	4	3	9	−1	1	
Sum	90	292	57	137	−33	127	$t = -3.26$
Mean	2.25		1.43		−0.83		$P < .01$
SD	1.51		1.20		1.60		

population, with the greatest reductions in asymmetry in the population with the largest discrepancy in right and left Q-angle measurements.

Conclusion

The insertion of a full-length, custom-made, flexible orthotic device significantly changes the Q-angle in asymptomatic pronating male subjects. Excessive pronation in Q-angle asymmetries can be effectively controlled or corrected by using orthotic devices. Further research examining the long-term effects of orthotic use on lower extremity biomechanics and determining whether these biomechanical changes are maintained after a course of orthotic use is suggested. Functional analysis of the interrelationship gait, Q-angle, and hyperpronation is recommended.

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C.R. BARD, INC. and DAVOL INC., Plaintiffs-Appellants, v. UNITED STATES SURGICAL CORP., Defendant-Appellee.

04-1135

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

388 F.3d 858; 2004 U.S. App. LEXIS 22738; 73 U.S.P.Q.2D (BNA) 1011

October 29, 2004, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the District of Delaware. Judge Kent A. Jordan. C.R. Bard, Inc. v. United States Surgical Corp., 107 F. Supp. 2d 489, 2000 U.S. Dist. LEXIS 10754 (D. Del., 2000)

DISPOSITION: Affirmed.

CASE SUMMARY

PROCEDURAL POSTURE: Appellant patent holder and its subsidiary sued appellee alleged patent infringer in the United States District Court for the District of Delaware, for patent infringement. The district court granted summary judgment that the alleged patent infringer did not infringe the claim literally or under the doctrine of equivalents. The patent holder and its subsidiary appealed.

OVERVIEW: The device claimed in the patent was an implant that was used to repair hernias that included a mesh plug with a conformable surface and mesh filler material inside the plug. The conformable surface allowed the plug to fill irregularly shaped hernia defects more completely than other plugs. The mesh filler material provided bulk and stiffness to the implant. In the intrinsic record, the claimed plug was consistently described as having pleats. The patent holder claimed that the alleged patent infringer made and sold a mesh plug that infringed the claim. On appeal, the court found that the patent holder clearly defined the plug in the claim as having pleats in both the specification and the prosecution history. Accordingly, the district court's claim construction properly found that the claim required pre-formed pleats. Furthermore, an analysis of the intrinsic record sufficed to support the construction, as the prosecution history provided an independent ground for construing the claim as requiring a plug with a pleated surface.

OUTCOME: The order of summary judgment was affirmed.

CORE TERMS: plug, pleated, patent, surface, mesh, specification, pleating, examiner, invention, embodiment, implant, pleat, hernia, reexamination, intrinsic, dictionary, conformable, inventive, conical, pliable, muscle, conform, tissue, configuration, pliability, interview, quotation, inventor, irregularities, prosthesis

LexisNexis(R) Headnotes

HN1 Determination of patent infringement requires a two-step analysis: (1) the scope of the claims must be construed; and (2) the allegedly infringing device must be compared to the construed claims. A district court's grant of summary judgment of non-infringement is also reviewed without deference.

HN2 A long line of cases indicates that the intrinsic record is the primary source for determining claim meaning. The intrinsic record includes the specification and the prosecution history. Under this approach to claim construction, evidence extrinsic to the patent document can shed useful light on the relevant art, but is less significant than the intrinsic record in determining the legally operative meaning of disputed claim language. Particularly, caselaw suggests that extrinsic evidence cannot alter any claim meaning discernible from intrinsic evidence.

HN3 Language in some of the United States Court of Appeals for the Federal Circuit's recent cases suggests that the intrinsic record, except for the claims, should be consulted only after the ordinary and customary meaning of claim terms to persons skilled in the pertinent art is determined. The language in these cases emphasizes technical and general-usage dictionaries in determining the ordinary meaning. Under this approach, where the ordinary meaning of a claim term is thus evident, the inventor's written description of the invention, for example, is relevant and controlling insofar as it provides clear lexicography or disavowal of the ordinary meaning.

HN4 The objective and contemporaneous record provided by the intrinsic evidence is the most reliable guide to help a court determine which of the possible meanings of the terms in question was intended by an inventor to particularly point out and distinctly claim an invention.

HN5 One representative definition of the term "conformable" is corresponding; similar.

HN6 A definition for the term "pliable" is easily bent, with synonyms including flexible and supple.

HN7 Courts regularly forgo detailed dictionary analyses if a term is commonplace.

HN8 Although a statement's location is not determinative, the location can signal the likelihood that the statement will support a limiting definition of a claim term. Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term. Statements that describe the invention as a whole are more likely to be found in certain sections of the specification, such as the Summary of the Invention. Accordingly, other things being equal, certain sections of the specification are more likely to contain statements that support a limiting definition of a claim term than other sections, although what import to give language from the specification must, of course, be determined on a case-by-case basis.

HN9 Under the United States Court of Appeals for the Federal Circuit's precedent, a patentee's choice of embodiments can shed light on the intended scope of a claim, but a patent claim term is not limited merely because the embodiments in the specification all contain a particular feature. On the other hand, a construction that excludes a preferred embodiment is rarely, if ever, correct.

COUNSEL: Claire Laporte, Foley Hoag LLP, of Boston, Massachusetts, argued for plaintiffs-appellants. With her on the brief was Peter B. Ellis.

Drew M. Wintringham, III, Clifford Chance US, LLP, of New York, New York, argued for defendant-appellee. With him on the brief was Mark W. Rueh.

JUDGES: Before NEWMAN, MICHEL, and PROST, Circuit Judges. Opinion for the court filed by Circuit Judge MICHEL. Opinion concurring-in-part and concurring in the result filed by Circuit Judge PROST.

OPINIONBY: MICHEL

OPINION:

[*859] MICHEL, Circuit Judge.